

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-111

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 4
 2. ANDA # 75-111
 3. NAME AND ADDRESS OF APPLICANT
ALPharma USPD (ALP)
333 Cassell Drive
Baltimore, MD 21224
 4. LEGAL BASIS FOR SUBMISSION
Expired patent and no marketing exclusivity period exists for the drug product per 16th Edition of Approved Drug Product.

Listed Drug Product: Atrovent by Boehringer Ingelheim
 5. SUPPLEMENT(s)
N/A
 6. PROPRIETARY NAME
None used
 7. NONPROPRIETARY NAME
Ipratropium Bromide Inhalation Solution
 8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
 9. AMENDMENTS AND OTHER DATES:
FIRM:
Original submission: 4-11-97
Major Amendment: 2-19-98
Amendment: 6-8-98
FAX Amendment: 10-16-98 (Response to 10-9-98 NA letter)
* Minor Amendment: 3-24-99

FDA:
Accepted for filing: 4-14-97 (Acknowledgment letter: 5-27-97)
NA letter: 9-22-97
NA letter with micro deficiencies: 10-9-98
NA letter: 12-24-98
 10. PHARMACOLOGICAL CATEGORY
Bronchodilator
 11. Rx or OTC
Rx
 12. RELATED IND/NDA/DMF(s)
- NDS
-
13. DOSAGE FORM
Solution
 14. POTENCY
0.02%
 15. CHEMICAL NAME AND STRUCTURE
See CR # 1.

16. RECORDS AND REPORTS

N/A

17. COMMENTS

Based on CR # 3, AP package was prepared by this reviewer and it was converted to NA (minor) based on GMP. Now EER status is satisfactory for all the firms, therefore, AP package is being prepared again.

This reviewer likes to clarify that no other changes are proposed in this amendment.

18. CONCLUSIONS AND RECOMMENDATIONS

Approved.

19. REVIEWER:

Mujahid L. Shaikh

DATE COMPLETED:

4-6-99

cc: AND 75-111
DUP File
Division File
Field Copy

Endorsements:

Mujahid L. Shaikh 4/9/99

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Commercial/Confidential
Information and are not
releasable.

Chem Rev 4

4/6/99